

MEDICATION GUIDE

ABILIFY[®] (a BIL ĭ fĭ)

Generic name: aripiprazole

Read this Medication Guide before you start taking ABILIFY and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about ABILIFY?

(For other side effects, also see “**What are the possible side effects of ABILIFY?**”).

Serious side effects may happen when you take ABILIFY, including:

- **Increased risk of death in elderly patients with dementia-related psychosis:** Medicines like ABILIFY can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY is not approved for the treatment of patients with dementia-related psychosis.
- **Risk of suicidal thoughts or actions:** Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:
 1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
 2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
 3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
 - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.

- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is ABILIFY?

ABILIFY is a prescription medicine used to treat:

- schizophrenia in people age 13 years and older.
- bipolar I disorder in people age 10 years and older, including:
 - manic or mixed episodes that happen with bipolar I disorder.
 - manic or mixed episodes that happen with bipolar I disorder, when used with the medicine lithium or valproate.
 - long-term treatment of bipolar I disorder.
- major depressive disorder in adults, as an add-on treatment to an antidepressant medicine when you do not get better with an antidepressant alone.
- irritability associated with autistic disorder in children and adolescents ages 6 to 17 years old.
- agitation associated with schizophrenia or bipolar disorder.

The symptoms of schizophrenia include:

- losing touch with reality (psychosis)
- seeing things or hearing voices that are not there (hallucinations)
- believing things that are not true (delusions)
- being suspicious (paranoia)
- disorganized speech and thinking
- bizarre behavior

The symptoms of bipolar I disorder include:

- extreme mood swings that include feeling depressed and high or irritable mood
- talking too fast and too much
- impulsive behavior
- having more energy and restlessness than usual
- needing less sleep than usual

The symptoms of major depressive disorder (MDD) include:

- feeling of sadness and emptiness
- loss of interest in activities that you once enjoyed and loss of energy
- problems focusing and making decisions
- feeling of worthlessness or guilt
- changes in sleep or eating patterns
- thoughts of death or suicide

The symptoms of irritability associated with autistic disorder include:

- aggressive behavior towards others
- intentionally trying to harm oneself
- temper tantrums
- quickly changing moods

The symptoms of agitation associated with schizophrenia or bipolar disorder include:

- hostility or aggressive behavior
- agitation and inner tension
- self-exhausting behavior

What should I tell my healthcare provider before taking ABILIFY?

Before taking ABILIFY, tell your healthcare provider if you have or had:

- diabetes or high blood sugar in you or your family; your healthcare provider should check your blood sugar before you start ABILIFY and also during therapy.
- seizures (convulsions).
- low or high blood pressure.
- heart problems or stroke.
- pregnancy or plans to become pregnant. It is not known if ABILIFY will harm your unborn baby.
- breast-feeding or plans to breast-feed. It is not known if ABILIFY will pass into your breast milk. You and your healthcare provider should decide if you will take ABILIFY or breast-feed. You should not do both.
- low white blood cell count.
- phenylketonuria. ABILIFY DISCMELT Orally Disintegrating Tablets contain phenylalanine.
- any other medical conditions.

Tell your healthcare provider about all the medicines that you take or recently have taken, including prescription medicines, non-prescription medicines, herbal supplements, and vitamins.

ABILIFY and other medicines may affect each other causing possible serious side effects. ABILIFY may affect the way other medicines work, and other medicines may affect how ABILIFY works.

Your healthcare provider can tell you if it is safe to take ABILIFY with your other medicines. Do not start or stop any medicines while taking ABILIFY without talking to

your healthcare provider first. Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ABILIFY?

- Take ABILIFY exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking ABILIFY yourself.
- ABILIFY can be taken with or without food.
- ABILIFY tablets should be swallowed whole.
- If you miss a dose of ABILIFY, take the missed dose as soon as you remember. If it is almost time for the next dose, just skip the missed dose and take your next dose at the regular time. Do not take two doses of ABILIFY at the same time.
- If you have been prescribed ABILIFY DISCMELT, take it as follows:
 - Do not open the blister until ready to take the DISCMELT tablet.
 - To remove one DISCMELT tablet, open the package and peel back the foil on the blister to expose the tablet.
 - Do not push the tablet through the foil because this could damage the tablet.
 - Immediately upon opening the blister, using dry hands, remove the tablet and place the entire ABILIFY DISCMELT Orally Disintegrating Tablet on the tongue.
 - Tablet disintegration occurs rapidly in saliva. It is recommended that ABILIFY DISCMELT be taken without liquid. However, if needed, it can be taken with liquid.
 - Do not attempt to split the DISCMELT tablet.
- If you take too much ABILIFY, call your healthcare provider or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

What should I avoid while taking ABILIFY?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ABILIFY affects you. ABILIFY may make you drowsy.
- Do not drink alcohol while taking ABILIFY.
- Avoid getting over-heated or dehydrated.
 - Do not over-exercise.
 - In hot weather, stay inside in a cool place if possible.
 - Stay out of the sun. Do not wear too much or heavy clothing.
 - Drink plenty of water.

What are the possible side effects of ABILIFY?

Serious side effects have been reported with ABILIFY including:

Also see “What is the most important information I should know about ABILIFY?” at the beginning of this Medication Guide.

- **Neuroleptic malignant syndrome (NMS):** Tell your healthcare provider right away if you have some or all of the following symptoms: high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare and serious condition that can lead to death. Call your healthcare provider right away if you have any of these symptoms.
- **High blood sugar (hyperglycemia):** Increases in blood sugar can happen in some people who take ABILIFY. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your healthcare provider should check your blood sugar before you start ABILIFY and during therapy.
- **Difficulty swallowing:** may lead to aspiration and choking.

Call your healthcare provider if you have any of these symptoms of high blood sugar while taking ABILIFY:

- feel very thirsty
- need to urinate more than usual
- feel very hungry
- feel weak or tired
- feel sick to your stomach
- feel confused, or your breath smells fruity.
- **Tardive dyskinesia:** Call your healthcare provider about any movements you cannot control in your face, tongue, or other body parts. These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking ABILIFY. Tardive dyskinesia may also start after you stop taking ABILIFY.
- **Orthostatic hypotension (decreased blood pressure):** lightheadedness or fainting when rising too quickly from a sitting or lying position.
- **Low white blood cell count**
- **Seizures (convulsions)**

Common side effects with ABILIFY in adults include:

- nausea
- vomiting
- constipation
- headache
- dizziness
- inner sense of restlessness/need to move (akathisia)
- anxiety
- insomnia
- restlessness

Common side effects with ABILIFY in children include:

- feeling sleepy
- headache
- vomiting
- fatigue
- increased appetite
- insomnia
- nausea
- stuffy nose
- weight gain
- uncontrolled movement such as restlessness, tremor, muscle stiffness

These are not all the possible side effects of ABILIFY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ABILIFY?

- Store ABILIFY at room temperature, between 59°F to 86°F (15°C to 30°C).
- Opened bottles of ABILIFY Oral Solution can be used for up to 6 months after opening, but not beyond the expiration date on the bottle.

Keep ABILIFY and all medicines out of the reach of children.

General information about ABILIFY

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ABILIFY for a condition for which it was not prescribed. Do not give ABILIFY to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about ABILIFY. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ABILIFY that was written for healthcare professionals. For more information about ABILIFY visit www.abilify.com.

What are the ingredients in ABILIFY?

Active ingredient: aripiprazole

Inactive ingredients:

Tablets: cornstarch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake.

ABILIFY DISCMELT Orally Disintegrating Tablets: acesulfame potassium, aspartame (which contains phenylalanine), calcium silicate, croscarmellose sodium, crospovidone, crème de vanilla (natural and artificial flavors), magnesium stearate, microcrystalline cellulose, silicon dioxide, tartaric acid, and xylitol. Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake.

ABILIFY Oral Solution: disodium edetate, fructose (200 mg per mL), glycerin, dl-lactic acid, methylparaben, propylene glycol, propylparaben, sodium hydroxide, sucrose (400 mg per mL), and purified water. The oral solution is flavored with natural orange cream and other natural flavors.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

ABILIFY is a trademark of Otsuka Pharmaceutical Company.



Bristol-Myers Squibb



Otsuka

Otsuka America Pharmaceutical, Inc.

1239550XX XXXXXXXX-XXXXXX

Rev Month Year

© 2010, Otsuka Pharmaceutical Co, Ltd, Tokyo, 101-8535 Japan